FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

CATHERINE STARK,

Plaintiff,

v. CIVIL ACTION NO. 2:13-cv-21637

BOSTON SCIENTIFIC CORPORATION,

Defendant.

MEMORANDUM OPINION AND ORDER
(*Daubert* Motions)

For reasons appearing to the court, it is **ORDERED** that the Memorandum Opinion and Order (Daubert Motions) [ECF No. 100] is **VACATED**. I enter the current Memorandum Opinion and Order to provide additional clarity on certain experts.

Throughout these MDLs, I have attempted to resolve all possible disputes before transfer or remand, including those related to the admissibility of expert testimony pursuant to *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993). Nevertheless, in some instances I face *Daubert* challenges where my interest in accuracy counsels reserving ruling until the reliability of an expert's testimonial opinion may be evaluated at trial. At trial, the opinions will be tested by precise questions asked and answered. The alternative of live *Daubert* hearings is impossible before transfer or remand because of the numerosity of such motions in these seven related MDLs. As these MDLs have grown and the expert testimony has multiplied,

I have become convinced that the critical gatekeeping function permitting or denying expert opinion testimony on decisive issues in these cases is best made with a live expert on the witness stand subject to vigorous examination.

In the course of examining a multitude of these very similar cases involving the same fields of expertise, I have faced irreconcilably divergent expert opinions offered by witnesses with impeccable credentials, suggesting, to me, an unreasonable risk of unreliability. The danger—and to my jaded eye, the near certainty—of the admission of "junk science" looms large in this mass litigation.

The parties regularly present out-of-context statements, after-the-fact rationalization of opinions, and incomplete deposition transcripts. This, combined with the parties' practice of recycling expert testimony, objections, and the court's prior rulings, creates the perfect storm of obfuscation. Where further clarity is necessary, I believe it is only achievable through live witnesses at trial and I therefore reserve ruling until expert opinions can be evaluated firsthand.

I. Background

This case resides in one of seven MDLs assigned to me by the Judicial Panel on Multidistrict Litigation ("MDL") concerning the use of transvaginal surgical mesh to treat pelvic organ prolapse ("POP") and stress urinary incontinence ("SUI"). In the seven MDLs, there are more than 75,000 cases currently pending, approximately 19,000 of which are in the Boston Scientific Corporation ("BSC") MDL, MDL No. 2326. The parties have retained experts to render opinions regarding the elements of the case's various causes of action, and the instant motions involve the parties' efforts to

exclude or limit the experts' opinions pursuant to *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993).

II. Legal Standard

Under Rule 702 of the Federal Rules of Evidence, expert testimony is admissible if the expert is "qualified . . . by knowledge, skill, experience, training, or education" and if his testimony is (1) helpful to the trier of fact in understanding the evidence or determining a fact in issue; (2) "based upon sufficient facts or data;" and (3) "the product of reliable principles and methods" that (4) have been reliably applied "to the facts of the case." Fed. R. Evid. 702. The Supreme Court has established a two-part test to govern the admissibility of expert testimony under Rule 702: the evidence is admitted if it "rests on a reliable foundation and is relevant." *Daubert*, 509 U.S. at 597. The proponent of expert testimony does not have the burden to "prove" anything to the court. *Md. Cas. Co. v. Therm-O-Disk, Inc.*, 137 F.3d 780, 783 (4th Cir. 1998). He or she must, however, "come forward with evidence from which the court can determine that the proffered testimony is properly admissible." *Id.*

The district court is the gatekeeper. "[E]xpert witnesses have the potential to be both powerful and quite misleading," so the court must "ensure that any and all scientific testimony . . . is not only relevant, but reliable." *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 199 (4th Cir. 2001) (citing *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 261 (4th Cir. 1999); *Daubert*, 509 U.S. at 588, 595). In carrying out this role, I "need not determine that the proffered expert testimony is irrefutable or certainly correct"—"[a]s with all other admissible evidence, expert testimony is subject to

testing by 'vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof.'" *United States v. Moreland*, 437 F.3d 424, 431 (4th Cir. 2006) (quoting *Daubert*, 509 U.S. at 596); *see also Md. Cas. Co.*, 137 F.3d at 783 (noting that "[a]ll *Daubert* demands is that the trial judge make a 'preliminary assessment' of whether the proffered testimony is both reliable . . . and helpful").

Daubert mentions specific factors to guide the court in making the overall reliability determinations that apply to expert evidence. These factors include (1) whether the particular scientific theory "can be (and has been) tested;" (2) whether the theory "has been subjected to peer review and publication;" (3) the "known or potential rate of error;" (4) the "existence and maintenance of standards controlling the technique's operation;" and (5) whether the technique has achieved "general acceptance" in the relevant scientific or expert community. *United States v. Crisp*, 324 F.3d 261, 266 (4th Cir. 2003) (quoting *Daubert*, 509 U.S. at 593–94). Despite these factors, "[t]he inquiry to be undertaken by the district court is 'a flexible one' focusing on the 'principles and methodology' employed by the expert, not on the conclusions reached." *Westberry*, 178 F.3d at 261 (quoting *Daubert*, 509 U.S. at 594–95); *see also Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 150 (1999) ("[T]he factors identified in *Daubert* may or may not be pertinent in assessing reliability, depending on the nature of the issue, the expert's particular expertise, and the subject of his testimony." (citation omitted)); *Crisp*, 324 F.3d at 266 (noting "that testing of reliability should be flexible and that *Daubert*'s five factors neither necessarily nor exclusively apply to every expert").

With respect to relevance, the second part of the analysis, *Daubert* further explains:

> Expert testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful. The consideration has been aptly described by Judge Becker as one of fit. Fit is not always obvious, and scientific validity for one purpose is not necessarily scientific validity for other, unrelated purposes. . . . Rule 702's helpfulness standard requires a valid scientific connection to the pertinent inquiry as a precondition to admissibility.

Daubert, 509 U.S. at 591–92 (citations and quotation marks omitted).

Ultimately, the district court has broad discretion in determining whether to admit or exclude expert testimony, and the "the trial judge must have considerable leeway in deciding in a particular case how to go about determining whether particular expert testimony is reliable." *Cooper*, 259 F.3d at 200 (quoting *Kumho Tire*, 526 U.S. at 152).

III. Preliminary Matters

I begin by addressing a few preliminary matters that affect many of the *Daubert* motions. First, both parties consistently challenge experts' opinions as improper state-of-mind or legal-conclusion testimony. As I have maintained throughout these MDLs, I will not permit the use of experts to usurp the jury's fact-finding function by allowing an expert to testify as to a party's knowledge, state of mind, or whether a party acted reasonably. *See, e.g.*, *In re C. R. Bard, Inc.*, 948 F. Supp. 2d 589, 611 (S.D. W. Va. 2013) (excluding expert opinions on the defendant's knowledge, state of mind, alleged bad acts, failures to act, and corporate conduct and ethics). The reasonableness of conduct and a party's then-existing state of mind "are

the sort of questions that lay jurors have been answering without expert assistance from time immemorial," and therefore, these matters are not appropriate for expert testimony. *Kidder v. Peabody & Co. v. IAG Int'l Acceptance Grp., N.V.*, 14 F. Supp. 2d 391, 404 (S.D.N.Y. 1998); *see also In re Rezulin Prods. Liab. Litig.*, 309 F. Supp. 2d 531, 546 (S.D.N.Y. 2004) ("Inferences about the intent and motive of parties or others lie outside the bounds of expert testimony.").[1] Likewise, "opinion testimony that states a legal standard or draws a legal conclusion by applying law to the facts is generally inadmissible." *United States v. McIver*, 470 F.3d 550, 562 (4th Cir. 2006). An expert may not state his opinion using "legal terms of art," such as "defective," "unreasonably dangerous," or "proximate cause." *See Perez v. Townsend Eng'g Co.*, 562 F. Supp. 2d 647, 652 (M.D. Pa. 2008).

I have diligently applied these rules to previous expert testimony, and I continue to apply them in this case. This does not mean that each objection to state-of-mind or legal-conclusion testimony raised in these motions is valid. But I will not parse the numerous reports and thousand-page depositions for each expert to determine the validity of these same objections. Instead, the onus is on counsel to tailor expert testimony at trial in accordance with the above directive. Therefore, unless otherwise necessary, the remainder of this opinion does not address objections

[1] On a related note, I caution the parties against introducing corporate evidence through expert witnesses. Although an expert may testify about his review of internal corporate documents solely for the purpose of explaining the basis for his or her opinions—assuming the opinions are otherwise admissible—he or she may not be offered solely as a conduit for corporate information. There is no reason why the plaintiff requires an expert to opine on such facts.

brought against an expert based on improper state-of-mind or legal-conclusion testimony.

I also note that several of the *Daubert* motions concern expert opinions entirely unrelated to the individual plaintiff at bar. For example, some experts have opined on general and specific causation with the specific causation portion of the opinion pertaining to wave plaintiffs other than the plaintiff in this particular case. In addition, the parties filed a total of thirteen *Daubert* motions involving, in many instances, duplicative experts. In an effort to remedy this problem of blanketed, duplicative *Daubert* motions, I directed the parties to file disclosures, indicating who, out of the thirteen challenged experts, they plan to call at trial for each case. *See* Pretrial Order No. 121, at 5–6 [ECF No. 62]. Through these disclosures, I hoped to gain a better understanding of the particular arguments at issue, thereby refining my *Daubert* rulings for the benefit of the receiving judge. Rather than aiding the court in this endeavor, however, the parties effectively ignored the pretrial order, identifying *all thirteen* of the challenged experts as probable expert witnesses. *See* BSC's Disclosure Required by Pretrial Order No. 121 [ECF No. 64]; Pl.'s Disclosure Required by Pretrial Order No. 121 [ECF No. 65]. Without guidance from the parties to the contrary, I have thus limited my review of the *Daubert* motions to only those arguments and opinions related to the instant plaintiff. In other words, I disregard arguments included in the briefing directed exclusively at other wave plaintiffs and, consequently, irrelevant to *this* case.

Finally, I am compelled to comment on the parties' misuse of my previous *Daubert* rulings on several of the experts offered in this case. *See generally Sanchez v. Boston Sci. Corp.*, No. 2:12-cv-05762, 2014 WL 4851989 (S.D. W. Va. Sept. 29, 2014); *Tyree v. Boston Sci. Corp.*, 54 F. Supp. 3d 501 (S.D. W. Va. 2014); *Eghnayem v. Boston Sci. Corp.*, 57 F. Supp. 3d 658 (S.D. W. Va. 2014). The parties have, for the most part, structured their *Daubert* arguments as a response to these prior rulings, rather than an autonomous challenge to or defense of an expert's opinion based on its reliability and relevance. In other words, the parties have comparatively examined each expert's opinions and have largely overlooked *Daubert*'s core considerations for assessing expert testimony. Although I recognize the tendency of my prior evidentiary determinations to influence subsequent motions practice, counsels' expectations that I align with these previous rulings when faced with a different record are remiss, especially when an expert has issued new reports and given additional deposition testimony.

Mindful of my role as gatekeeper of expert testimony, as well as my duty to "respect[ ] the individuality" of each MDL case, *see In re Phenylpropanolamine Prods. Liab. Litig.*, 460 F.3d 1217, 1231 (9th Cir. 2006), I refuse to credit *Daubert* arguments that simply react to the court's rulings in *Sanchez* and its progeny. Indeed, I feel bound by these earlier cases only to the extent that the expert opinions and *Daubert* objections presented to the court then are identical to those presented now. Otherwise, I assess the parties' *Daubert* arguments anew. That is, in light of the particular opinions and objections currently before me, I assess "whether the

reasoning or methodology underlying the testimony is scientifically valid" and "whether that reasoning or methodology properly can be applied to the facts in issue." *Daubert*, 509 U.S. at 592–93. Any departure from *Sanchez*, *Eghnayem*, or *Tyree* does not constitute a "reversal" of these decisions and is instead the expected result of the parties' submission of updated expert reports and new objections to the opinions contained therein.

IV. BSC's *Daubert* Motions

In this case, BSC seeks to limit or exclude the expert opinions of Drs. Michael Thomas Margolis, Thomas Barker, Jimmy Mays, Peggy Pence, Russell Dunn, Scott Guelcher, Richard Trepeta, Vladimir Iakovlev, Jerry Blaivas, and William Porter.

A. Michael Thomas Margolis, M.D.

BSC seeks to exclude the testimony of Michael Thomas Margolis, M.D. Dr. Margolis is a pelvic floor surgeon and urogynecologist who offers general causation opinions in this case.

1. Failure to Consider Studies

First, BSC challenges Dr. Margolis's failure to consider contrary studies. Dr. Margolis has explained his methodology for giving less credence to certain studies than to others. Dr. Margolis states that he has examined other studies that counter his own opinions. To the extent the defendant challenges the reasons Dr. Margolis offers for not relying on certain studies, such challenges go to the weight of Dr. Margolis's opinions, not their admissibility. The defendant is free to cross-examine

Dr. Margolis regarding studies that cut against his opinions. The defendant's motion is **DENIED** on this point.

Second, BSC challenges Dr. Margolis's opinion that there is a greater than 50 percent complication rate of pain in women with polypropylene mesh and slings. In his deposition, Dr. Margolis acknowledges that contrary studies exist, and I do not doubt that Dr. Margolis reviewed contrary studies. However, his methodology may be flawed if he does not provide an adequate explanation for why he disagrees with those studies. There is no such explanation in this case. Therefore, Dr. Margolis's opinion that more than 50 percent of women implanted with mesh experience pain is **EXCLUDED** as unreliable. This aspect of BSC's motion is **GRANTED**.

Third, BSC challenges Dr. Margolis's general opinions that complications in women with polypropylene mesh products are high. Dr. Margolis explains that, when forming his opinion about the complication rates of a medical procedure, he gives the benefit of the doubt to the patient. In other words, he assumes the worst-case scenario and errs on the side of opining as to a higher complication rate to better protect a patient. This is not a reliable, scientific basis for determining the complication rates associated with a mesh device. The plaintiff has failed to demonstrate that Dr. Margolis has sufficient scientific support to opine as to these generalized statements. Therefore, this testimony is **EXCLUDED**, and this part of BSC's motion is **GRANTED**.

2. **Lack of Scientific Basis**

BSC also argues that Dr. Margolis failed to provide any scientific basis for his other opinions. The plaintiff does not address the majority of BSC's arguments on this point, and I decline to raise counterarguments for the plaintiff when she has failed to address BSC's arguments in her briefing. The plaintiff has not "come forward with evidence from which the court can determine that the proffered testimony is properly admissible." *Md. Cas. Co. v. Therm-O-Disk, Inc.*, 137 F.3d 780, 783 (4th Cir. 1998). Therefore, the following opinions from Dr. Margolis are **EXCLUDED**: (1) that the Burch procedure is more effective than polypropylene mesh slings; (2) that Xenform slings are more effective than polypropylene slings; (3) that the infection rate of polypropylene mesh is up to 100 percent; (4) that the complication rate of urethral obstruction is greater than 10 percent with polypropylene mid-urethral slings; and (5) that he has removed 10 to 15 percent of BSC products. These portions of BSC's motion are **GRANTED**.

Unlike the above opinions, the plaintiff appears to respond to BSC's argument concerning Dr. Margolis's opinion about a lack of scientific support for the use of mesh. The plaintiff contends that Dr. Margolis merely opines that there is a lack of *long-term* data. Contradictions in testimony should be addressed on cross-examination. *See Daubert*, 509 U.S. at 596 ("Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence.").

Therefore, I do not exclude Dr. Margolis's opinion on a lack of *long-term* data on reliability grounds.[2] Therefore, BSC's motion regarding this opinion is **DENIED**.

3. Expertise

BSC argues that Dr. Margolis offers opinions outside the scope of his qualifications on (1) biomaterials; (2) polypropylene degradation; (3) foreign body reaction; (4) adequate pore size; (5) adequate weight of polypropylene; (6) biocompatibility of polypropylene; (7) medical device design and development; and/or (8) marketing. The plaintiff fails to provide any argument addressing how Dr. Margolis is an expert on any of the above subject matters, beyond the basic assertion that Dr. Margolis is an established urogynecologist with years of experience with pelvic mesh products. I will not make arguments for the plaintiff. Therefore, this aspect of BSC's motion is **GRANTED**.

4. Undisclosed Opinions

Finally, BSC argues that Dr. Margolis seeks to offer opinions that were not disclosed in his expert report and that Dr. Margolis seeks to discuss materials that were not cited to in his expert report. Testimony on direct examination using such undisclosed sources as support for his opinions is **EXCLUDED** on Rule 26 grounds. However, the court notes that two articles that BSC alleges were not disclosed—

[2] The plaintiffs in prior cases have responded to this same challenge in a different way. *See Sanchez*, 2014 WL 4851989, at *14; *Tyree*, 54 F. Supp. 3d at 519–27; *Eghnayem*, 57 F. Supp. 3d at 676–80. Instead of focusing on long-term data, those plaintiffs informed the court that Dr. Margolis never opined that there was *no* data supporting the benefits of polypropylene mesh, but just that there was no *credible* data on this subject. In those cases, I excluded Dr. Margolis's opinion because "it [was] still unclear why Dr. Margolis believe[d] th[o]se studies lack[ed] credibility." *Sanchez*, 2014 WL 4851989, at *14.

Vaginal Mesh Contraction: Definition, Clinical Presentation and Management and *Surgical Management of Pelvic Organ Prolapse in Women*—were included in Dr. Margolis's relied-upon list. Dr. Margolis's testimony on these two articles is not excluded under *Daubert*. Therefore, I find that this aspect of BSC's motion is **GRANTED in part** and **DENIED in part**.

For the reasons stated above, I **GRANT in part** and **DENY in part** BSC's Motion to Exclude the Testimony of Michael Thomas Margolis, M.D.

B. Thomas H. Barker, Ph.D.

The plaintiff offers Dr. Barker as a biomaterials expert. He seeks to testify as to general opinions, such as those related to the biocompatibility of polypropylene mesh, mesh degradation, scar formation, mesh design, and mesh testing.

1. Reliability

a. Mechanical Mismatch

Dr. Barker opines that there is a mechanical mismatch between vaginal tissue and BSC mesh. I find this opinion to be unreliable. In comparing the elastic moduli of vaginal tissue to that of mesh in order to support his opinion as to a mismatch, Dr. Barker relied on a study finding six to seven kilopascals for vaginal tissue. However, he admits that he has no scientific basis for forming a kilopascal number for BSC mesh. Such an opinion rests on an unreliable basis. To the extent that Dr. Barker merely opines that vaginal tissue and polypropylene mesh are not composed of the same material, such an opinion is not helpful to a jury. Dr. Barker's opinion that a mechanical mismatch exists is **EXCLUDED**.

b. Mechanical Performance Findings

Dr. Barker's opinions on the clinical consequences resulting from the alleged mechanical mismatch between the mesh and the human body are **EXCLUDED** as unreliable as well. His opinion on the mechanical mismatch generally is excluded, and, thus, any derivative opinions are also unreliable. Such opinions are too speculative to be deemed reliable under *Daubert*.

Moreover, with respect to mesh deformation in particular, BSC challenges Dr. Barker's opinion that BSC testing revealed approximately 35 percent to 52 percent of deformation in its mesh samples. However, when questioned about this topic at his deposition, Dr. Barker admitted that he is unsure whether this testing was done exclusively on BSC products. This deposition testimony further reveals the unreliability of Dr. Barker's methodology. BSC's motion with respect to Dr. Barker's opinions on the clinical effects of a mechanical mismatch between BSC mesh and vaginal tissue is **GRANTED**.

In conclusion, BSC's Motion to Exclude the Opinions and Testimony of Thomas H. Barker, Ph.D. is **GRANTED**.

C. Jimmy W. Mays, Ph.D.

Dr. Mays is a Distinguished Professor of Chemistry at the University of Tennessee who offers general causation opinions on the following issues: (1) the chemical structure and properties of polypropylene; (2) degradation of polypropylene by thermo-oxidative processes and in vivo; and (3) the effect of in vivo degradation on

the polypropylene implant.[3]

BSC argues that Dr. Mays's opinions should be excluded because his thermogravimetric analysis ("TGA") did not replicate the in vivo environment. Dr. Mays produced certain results while testing polypropylene at very high temperatures. He then concluded that the same results will occur inside the human body at much lower temperatures, but he did not provide any explanation or support for his opinion. These derivative conclusions are not the product of reliable principles and methods. Dr. Mays failed to demonstrate a reliable connection between his TGA results and his conclusions about polypropylene degradation in the human body. Accordingly, BSC's Motion to Exclude the Opinions and Testimony of Jimmy W. Mays, Ph.D. is **GRANTED**, and Dr. Mays's general causation opinions based on his TGA are **EXCLUDED**.

D. Peggy Pence, Ph.D.

Dr. Pence works as a clinical and regulatory consultant, providing advice, guidance, and product development services to pharmaceutical/biopharmaceutical and medical device companies in the areas of strategic planning, preclinical testing, clinical trials, design and conduct, and regulatory matters involving the FDA.

1. Qualifications

BSC maintains that Dr. Pence's work as a researcher and consultant on the

[3] As an initial matter, BSC attempts to incorporate by reference its *Daubert* objections to Dr. Mays's general causation opinions offered in *Sanchez v. Boston Scientific Corp.* BSC does not inform the court what these objections are or attach the *Sanchez* motion. Further, the expert report offered in *Sanchez* was authored by both Dr. Mays and Dr. Gido and is not identical to the report offered in the present case. Accordingly, I will not address the objections made in *Sanchez* and instead rule solely on the issues currently before me.

development of medical products does not qualify her to opine about the safety and efficacy of mesh products, as she attempts to do in her expert report. Dr. Pence has over forty years of experience in the research and development of medical devices. Over that time, she has accumulated knowledge that is relevant to this case, such as the design of clinical trials for diseases of the female genital system, the clinical testing of novel medical devices, and the content of product labeling. Accordingly, I **FIND** that Dr. Pence is qualified to render the opinions set forth in her expert report.

2. General Objections

I begin by addressing two objections that BSC raises multiple times throughout its motion, all related to the reliability of the authoritative sources underlying Dr. Pence's opinions, which include a 2006 study by the French National Authority for Health ("HAS"), the recommendations of the National Institute for Health and Care Excellence ("NICE"), and the various guidance documents drafted by the Global Harmonization Task Force ("GHTF").[4] BSC has not cited any case suggesting that the binding effect of industry standards dictates their reliability. Indeed, the Seventh Circuit Court of Appeals has suggested the opposite:

> [T]he relevant question for admissibility purposes is not whether the . . . guidelines are controlling in the sense of an industry code, or even how persuasive they are. It is only whether consulting them is a methodologically sound practice on which to base an expert opinion in the context of this case.

[4] The GHTF, which was conceived in 1992 and replaced by the International Medical Device Regulators Forum ("IMDRF") in 2011, represented a partnership between regulatory authorities and regulated industry and sought to achieve greater uniformity between national medical device regulatory systems. The European Union, United States, Canada, Australia, and Japan were the founding members, and these entities, as well as Brazil, China, Japan, and Russia, currently form the Management Committee of the IMDRF. Dr. Pence relies on several GHTF "Final Documents" in reaching her opinions.

Lees v. Carthage Coll., 714 F.3d 516, 525 (7th Cir. 2013). Accordingly, I give no import to the non-binding nature of the HAS, NICE, and GHTF recommendations in my *Daubert* analysis and instead focus on whether Dr. Pence's reliance on these sources constitutes a methodologically sound practice.

BSC also attempts to equate GHTF standards with FDA regulations and asserts that, like FDA regulations, admission of GHTF standards, which have "regulatory purpose, history, and focus," could confuse and mislead the jury. GHTF standards do not carry the same prejudicial force—the government does not promulgate them, manufacturers are not bound by them, and jurors are not familiar with them. Although the FDA appears to have had a limited role in the activities of the GHTF, that role was not instrumental or definitive, and the work of the GHTF can be described without reference to the FDA. Accordingly, I **FIND** BSC's argument without merit.

3. Premarket Testing

Generally, BSC contends that none of the studies Dr. Pence relies on support her opinion that BSC should have performed premarket clinical trials. My review of the exhibits, however, indicates that several guidance documents supply a basis for this opinion. Additionally, although the NICE and HAS studies are not as explicit as the GHTF documents, they both emphasize the importance of clinical trials in assessing a product's safety for surgical use. Furthermore, all of these documents carry the indicia of reliability set forth by *Daubert*: the conclusions were reached after documented and validated testing, the results were published, and the testing was

conducted through a defined methodology described in each paper. Therefore, I **FIND** Dr. Pence's consultation of these sources in reaching her opinion both justified and reliable.

Next, BSC argues that Dr. Pence's report lacks a discussion of the GHTF standard itself and how Dr. Pence's application of that standard led her to form the opinions contained in her report. These remaining arguments go to the weight of Dr. Pence's testimony, not its reliability, and are therefore better suited for cross-examination. In conclusion, I **DENY** BSC's motion to exclude Dr. Pence's opinion on premarket clinical testing.

4. Product Labels

BSC asserts that to the extent Dr. Pence's opinions on product labeling relate to BSC's deviation from the branding requirements of the Food, Drug, and Cosmetic Act ("FDCA"), they should be excluded. I agree. As I have held several times in the course of these MDLs, expert testimony about the requirements of the FDCA, which are not at issue in this case, could lead to more confusion about the state tort claims than enlightenment. I cannot admit Dr. Pence's testimony as it relates to the FDCA or FDA regulations. *See Lewis v. Johnson & Johnson*, 991 F. Supp. 2d 748, 755 (S.D. W. Va. 2014) (agreeing that "alleged shortcomings in FDA procedures are not probative to a state law products liability claim"). These opinions are **EXCLUDED**.

This finding, however, does not result in the exclusion of Dr. Pence's opinion on product labeling altogether because, unlike in previous cases, Dr. Pence has a second source of information that is unrelated to the FDA (i.e., the GHTF's *Label and Instructions for Use for Medical Devices*) which I must also consider in my analysis.

The GHTF document on product labels does not state—expressly or otherwise—that manufacturers should include the severity, frequency, and permanency of adverse events in a warning, nor does it state that a label should qualify the difficulty of removing the device. Furthermore, Dr. Pence does not explain how this document could be interpreted as such. Seeing no non-FDA grounds for Dr. Pence's opinion that BSC should have included this particular information in its labels, I **FIND** it unreliable, and it is therefore **EXCLUDED**.[5]

With respect to Dr. Pence's remaining opinions on product labeling, BSC moves for exclusion because Dr. Pence never spoke to any physicians about this issue. An expert's failure to examine a particular source of information is not grounds for exclusion under *Daubert* so long as the expert has other "sufficient facts or data" to support her opinion. Fed. R. Evid. 702. Here, Dr. Pence considered the GHTF's *Label and Instructions for Use for Medical Devices*, the DFU, several BSC internal documents, and other medical and scientific literature. I find this collection of sources sufficient for the purposes of *Daubert*. BSC has ample grounds to cross-examine and impeach Dr. Pence at trial regarding any perceived oversights in her analysis.

5. Post-Market Vigilance

In arriving at her post-market vigilance opinions, Dr. Pence exclusively considered data from the FDA's MAUDE database.[6] As I have previously explained,

[5] BSC raises this objection only to Dr. Pence's opinions that the label should have included information on the difficulty of mesh removal and the permanency, severity, and frequency of adverse events. My holding is therefore limited to these specific opinions as well.

[6] "The MAUDE database houses medical device reports submitted to the FDA by mandatory reporters (manufacturers, importers and device user facilities) and voluntary reporters such as health care professionals, patients and consumers." FDA, *MAUDE—Manufacturer and User Facility Device*

BSC's communication, or alleged lack thereof, with the FDA through the MAUDE database has "no bearing on whether BSC provided adequate warnings or whether its products were defective." *Sanchez*, 2014 WL 4851989, at *36. Any opinion based on data collected in the MAUDE database, which acts as an arm of the FDA, is not helpful to the jury and is therefore inadmissible. *See* Fed. R. Evid. 702 (stating that the expert's specialized knowledge must "help the trier of fact to understand the evidence or to determine a fact in issue"). Because Dr. Pence's opinion on post-market vigilance appears to be entirely based on data—or lack thereof—found in the MAUDE database, I find it unreliable. Without a reliable basis, Dr. Pence's opinion on BSC's inadequate post-market vigilance is **EXCLUDED**, and BSC's motion on this matter is **GRANTED**.

6. Final Caveat: Relevance

BSC argues that several of the standards Dr. Pence relies on were not published until after the device at issue was marketed, making those standards irrelevant to this case. I **RESERVE** ruling on this matter until trial.

In sum, BSC's Motion to Exclude the Opinions and Testimony of Peggy Pence, Ph.D. is **GRANTED in part, DENIED in part**, and **RESERVED in part**. BSC's objection to Dr. Pence's opinions on the alleged carcinogenicity of polypropylene, uncontested by the plaintiff, is **GRANTED**.

E. Russell Dunn, Ph.D.

Experience, http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/Search.cfm (last visited April 3, 2016).

Dr. Dunn is a registered professional engineer and the president and founder of Polymer Chemical Technologies LLC, a company that focuses on process and product design issues, process and product safety, and polymer product analysis.

BSC argues that Dr. Dunn is not qualified to offer opinions concerning the design, risk management, or manufacture of polypropylene mesh devices. Dr. Dunn's company, Polymer Chemical Technologies LLC, has been involved in over 200 projects focusing on polymer product design; however, none of these projects has involved a medical device. Dr. Dunn also teaches five different chemical engineering courses at Vanderbilt University; however, he has never taught a course specific to medical devices or polypropylene. Similarly, Dr. Dunn states that he has a tremendous amount of experience assessing risk through Failure Mode and Effects Analysis ("FMEA"), but then admits that he has never been involved in developing an FMEA for a medical device. Finally, Dr. Dunn has authored many publications throughout his career; however, not one of these publications examines medical devices or how polypropylene behaves as part of a medical device.

All of Dr. Dunn's opinions are premised on his belief that the polypropylene mesh in BSC's devices will undergo oxidative degradation in the body, yet Dr. Dunn admits that he is not an expert in biomaterials or biocompatibility and that he is not qualified to opine on the way polypropylene may affect the body physiologically. I find that Dr. Dunn does not have the requisite skill, knowledge, training, education, or experience to qualify as an expert in this case, and his opinions are **EXCLUDED**. Accordingly, BSC's Motion to Exclude the Opinions and Testimony of Russell Dunn,

Ph.D. is **GRANTED**.

F. Scott Guelcher, Ph.D.

Dr. Guelcher is a chemical engineer offered by the plaintiff to opine on how the human body responds to polypropylene once it is implanted and the reactions that occur on the surface of the implant. Dr. Guelcher's opinions—to the extent they are based on Dr. Dunn's testing—are **EXCLUDED** because Dr. Dunn's testing is unreliable. Dr. Dunn's *in vitro* testing failed to follow the written protocol he relied upon in developing his test—the very protocol that Dr. Guelcher developed. Specifically, Dr. Dunn could not account for why he changed the testing solution once a week when the protocol called for changing the solution once every three days. Further, Dr. Dunn stated in his deposition that he would only use his testing to show the general behavior of polypropylene mesh in an *in vitro* oxidizing medium—not to extend what that means inside the body. Dr. Dunn's testing lacks sufficient indicia of reliability. Therefore, BSC's Motion to Exclude the Opinions and Testimony of Scott Guelcher, Ph.D. is **GRANTED**.

G. Richard Trepeta, M.D.

Richard Trepeta, M.D., is, among other things, a board-certified pathologist and a Fellow with the College of American Pathologists and the International Society for the Study of Vulvovaginal Disease.

1. Qualifications

First, BSC objects to Dr. Trepeta's opinion testimony on the properties of polypropylene mesh. Given Dr. Trepeta's knowledge and experience as an anatomical

and clinical pathologist, I find him qualified to testify about mesh degradation, mesh shrinkage, and mesh migration, and I therefore **DENY** BSC's motion in this respect.

Second, BSC objects to Dr. Trepeta's testimony on the human clinical response to mesh implants. Dr. Trepeta's extensive experience and knowledge in the field of pathology qualify him to submit these opinions. Part of pathology involves reaching a diagnosis through clinical and pathologic correlation. Dr. Trepeta frequently engages in this process by providing clinical consultations to physicians, which require him to examine clinical information (through specimens, reports, or physician findings) and reach a pathologic diagnosis about a patient. Dr. Trepeta's understanding and application of the pathologic process qualify him to opine on the causal relationship between transvaginal mesh implantation and tissue response. Therefore, I **DENY** BSC's motion as to Dr. Trepeta's qualifications on this point.

2. Reliability and Relevance

BSC raises two objections to the reliability and relevance of Dr. Trepeta's opinion testimony.

a. Reliability

BSC contends that Dr. Trepeta's method of using pathology reports to formulate his opinions is unreliable. Dr. Trepeta used various resources to reach his expert opinion: (1) he has studied over fifty mesh explant samples in his private practice; (2) he has studied the medical literature on mesh implantation and determined that his pathological findings corresponded with the published research on mesh erosion and exposure in the vaginal wall; and (3) he has reviewed twenty-

four pathology reports that he received from the plaintiff's counsel and ascertained that the pathology reports of excised Boston Scientific products are consistent with the acute, sub-acute, and chronic categories of the disease process.

Dr. Trepeta's review of the pathology reports has a fatal deficiency—it lacked standards to govern the process of selecting the sample of pathology reports to be evaluated. The plaintiff does not explain how or why she chose these twenty-four reports for Dr. Trepeta's review, and without such an explanation, I have no way of assessing the potential rate of error or the presence of bias. Accordingly, Dr. Trepeta's opinions derived solely from his review of the twenty-four pathology reports are **EXCLUDED**. BSC is free to cross-examine Dr. Trepeta at trial to ensure the basis of his opinions is consistent with the court's ruling.

b. Litigation Driven

BSC argues Dr. Trepeta's opinions are unreliable because they are litigation driven. I will not exclude an expert on the sole basis that the opinion arose during litigation, so long as it is otherwise reliable. BSC's Motion is **DENIED** on this point.

In conclusion, Dr. Trepeta's general causation opinions are admitted except for his opinions based on the pathologic reports selected by the plaintiff's counsel for his review, which are excluded. Accordingly, BSC's Motion to Exclude the Opinions and Testimony of Dr. Trepeta is **GRANTED in part** and **DENIED in part**.

H. Vladimir Iakovlev, M.D.

Dr. Iakovlev is an anatomical pathologist and director of Cytopathology at the Department of Laboratory Medicine at St. Michael's Hospital in Toronto, Canada.

1. General Causation

BSC contends that this court should exclude Dr. Iakovlev's opinions on specimens other than the plaintiff's. Dr. Iakovlev's general causation opinions are based largely on his examination of the mesh explant samples in his personal data pool. However, Dr. Iakovlev provides no information on how the mesh explants were chosen or prepared for examination. Dr. Iakovlev testified that plaintiff's counsel provided approximately 70 percent of the transvaginal mesh explants, but he does not know how those explants were chosen or what methodology counsel employed.

Accordingly, BSC's motion on this matter is **GRANTED**, and Dr. Iakovlev's general causation opinions based on his data pool are **EXCLUDED**.

2. Specific Causation

It is unclear whether Dr. Iakovlev intends to offer a specific causation opinion in this case because the court has not been provided with an expert report from Dr. Iakovlev specific to this plaintiff. In this case, there is no evidence that Dr. Iakovlev examined the plaintiff's explanted mesh, performed a physical examination, or otherwise conducted a differential diagnosis. Assuming Dr. Iakovlev seeks to offer specific causation opinions, such opinions are not sufficiently reliable under *Daubert* and are thus **EXCLUDED**.

In conclusion, BSC's Motion to Strike and Exclude the Opinions and Testimony of Vladimir Iakovlev, M.D. is **GRANTED**.

I. Jerry Blaivas, M.D.

Dr. Blaivas is a pelvic surgeon and urologist. The plaintiff offers Dr. Blaivas to opine as to general causation. He renders several opinions, including those related to

the complications associated with polypropylene mesh slings and the Obtryx, the safety and efficacy of synthetic slings as compared to non-mesh procedures, and BSC's warnings to physicians and patients.

1. Opinion that Polypropylene Mid-Urethral Slings Are Not Safe in the Treatment of SUI

BSC challenges Dr. Blaivas's opinion that polypropylene mid-urethral slings are not safe in the treatment of SUI. I **EXCLUDE** Dr. Blaivas's opinion because Dr. Blaivas applied standards different than those he applies in his medical practice. In his deposition, Dr. Blaivas was confronted with a statement he had previously made in a peer-reviewed article that contradicts his safety opinion proffered in this case. Dr. Blaivas explains that "I phrase my words differently in the peer-reviewed literature than I do in the legal literature because it's two different sets of rules." Blaivas Dep. 391:20–24, Dec. 15, 2014. He states, "I can offer a different opinion with a reasonable degree of medical certainty than I can in the peer-reviewed literature which requires, in my judgment, a higher degree of certainty than a reasonable degree." *Id.* at 391:14–19.

The above deposition testimony plainly reveals that Dr. Blaivas employed less intellectual rigor in forming this opinion as an expert witness than he employs when writing studies in his field. Such admission renders Dr. Blaivas's methodology unreliable. As a result, BSC's motion with respect to this opinion is **GRANTED**.

2. Opinion on Design of Polypropylene Mesh Slings

Next, BSC challenges Dr. Blaivas's opinion on the design of polypropylene mesh slings. I agree with BSC that Dr. Blaivas lacks qualifications to be deemed an

expert in the design of a medical device. The plaintiff contends that Dr. Blaivas's surgical experience with similar slings renders him qualified. This experience alone, however, insufficiently establishes his design qualifications. Thus, his opinions related to product design are **EXCLUDED**.

3. BSC Alleges that Dr. Blaivas Seeks to Offer Opinions Outside Area of Expertise

BSC argues that Dr. Blaivas seeks to offer opinions on mesh shrinkage, degradation, and the MSDS that are outside his area of expertise. Above, I exclude Dr. Blaivas's opinion that polypropylene mid-urethral slings are not safe in the treatment of SUI on reliability grounds. Therefore, I need not address Dr. Blaivas's qualifications on shrinkage and degradation.

As for the MSDS, BSC seeks to exclude Dr. Blaivas's opinion that the polypropylene mesh used in the Obtryx, Obtryx Curved, and Obtryx Halo was never meant to be implanted inside the human body per the MSDS. The plaintiff fails to respond to this argument, and I presume that the plaintiff concedes that Dr. Blaivas will not offer such an opinion at trial. I decline to raise counterarguments on her behalf. Thus, BSC's motion with respect to Dr. Blaivas's MSDS opinion is **GRANTED**.

4. Specific Causation

Although BSC argues that Dr. Blaivas's specific causation opinions should be excluded, Dr. Blaivas is not a specific causation expert in this case. Therefore, BSC's motion with respect to this matter is **DENIED**.

In conclusion, BSC's Motion to Exclude the Opinions and Testimony of Jerry Blaivas, M.D. is **GRANTED in part** and **DENIED in part**.

J. William Porter, M.D.

Dr. Porter is a urogynecologist offered as an expert witness on the specific causation of the plaintiff's injuries. BSC argues that Dr. Porter's expert report goes beyond specific causation opinions and into subject matter about which he is unqualified to provide expert opinions. Additionally, BSC contends that Dr. Porter did not conduct a proper differential diagnosis, and as a result, his specific causation opinion is unreliable.

1. Qualifications

BSC argues that Dr. Porter is unqualified to opine on mesh degradation because he conceded he was not an expert in polymer science or what happens to mesh on a molecular level. However, a urogynecologist's extensive experience with performing mesh implant and explant surgeries—as exhibited by Dr. Porter—can qualify him to opine on how the product reacts inside the body. Additionally, that he has no experience in polymer science is irrelevant because Dr. Porter is not offering opinions about "what's happening at the molecular level." Porter Dep., Dec. 2, 2014, 225:19–227:19. Rather, he considers mesh degradation on a large scale, focusing on the ways a polypropylene mesh product can change after implantation in the human body. His fifteen-year career as a pelvic surgeon qualifies him to render these opinions to the extent they are applicable to his differential diagnosis in this specific case. BSC's Motion as to qualification is **DENIED**.

2. Reliability of Specific Causation Opinion

BSC challenges the reliability of Dr. Porter's opinion on the specific causation

of the plaintiff's injuries. Although Dr. Porter states that he performed a differential diagnosis, his expert report reveals an inconsistency as to whether he could or could not rule out the plaintiff's "previous hysterectomy, cystocele, or trauma from vaginal birth delivery" as "the source" of the plaintiff's injuries. Porter Expert Report VII [ECF No. 69-1]. At best, Dr. Porter's opinions are extremely vulnerable to cross-examination. Even so, because he performed a differential diagnosis and clearly considered other possible causes for the plaintiff's injuries, I **RESERVE** ruling on the admissibility of his specific causation opinion until trial.

V. The Plaintiff's *Daubert* Motions

In this case, the plaintiff seeks to limit or exclude the expert opinions of Drs. Gary L. Winn, Christine Brauer, and Lonny Green.

A. Gary L. Winn, Ph.D.

Dr. Winn is a professor in Industrial and Management Systems Engineering in the Safety Management program at West Virginia University. Dr. Winn offers expert opinions with regard to the nature and purpose of Material Safety Data Sheets (MSDS) generally, and specifically as to the MSDS for the polypropylene used by BSC in the manufacture of its pelvic mesh products. The plaintiff argues that Dr. Winn's opinions should be excluded entirely, consistent with this court's decisions in *Tyree* and *Eghnayem* because his expert report is identical to the reports filed and excluded in those two cases.[7] BSC has not presented any new arguments to convince me that

[7] In *Tyree*, I ruled as follows:

> In his expert report, Dr. Winn describes (1) the development of the hazard communication standard; (2) the standardization of the content of MSDSs; and (3) uses of MSDSs in the field. Dr. Winn concludes that raw polypropylene is not hazardous

Dr. Winn is warranted as an independent expert. However, I acknowledge the potential need for rebuttal testimony based on what the plaintiff presents at trial. Accordingly, I **RESERVE** ruling on the admissibility of Dr. Winn's expert opinions for trial.

B. Christine Brauer, Ph.D.

Dr. Brauer is the President of Brauer Device Consultants LLC, where she provides consulting services to the medical device industry regarding FDA regulatory requirements. The plaintiff seeks to exclude both of Dr. Brauer's expert reports filed on November 21, 2014. The first report ("FDA report") focuses on the FDA regulatory framework for surgical devices, and the second report ("supplemental report") focuses on industry standards that a manufacturer of a medical device must meet. I have repeatedly and thoroughly considered the admissibility of the FDA's 510(k) process, and I have consistently found that the 510(k) process does not relate to safety or efficacy. Therefore, the parties may not present evidence regarding the 510(k) clearance process or subsequent FDA enforcement actions. Accordingly, the plaintiff's motion with regard to Dr. Brauer's FDA report is **GRANTED**, and her opinions set

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based on anecdotal evidence involving other MSDSs; and therefore, the 2004 Chevron Phillips MSDS is extraneous. Although I believe that the warning provided in the MSDS is relevant, I do not believe an expert is required to discuss MSDSs generally or the issue of whether polypropylene requires an MSDS because of its hazardous nature. A narrative review of the history and development of MSDSs and who uses them in the field is not helpful to the jury. The pertinent issue is that the MSDS contained a warning (Medical Application Caution) allegedly not heeded by BSC, not that an MSDS itself existed. This warning from the supplier could have taken any form. Accordingly, I **FIND** that Dr. Winn's opinions regarding MSDSs should be excluded in their entirety.

2014 WL 5320566, at *63; *see also Eghnayem*, 2014 WL 5461991, at *61 (quoting *Tyree*).

forth in that report are **EXCLUDED**.

With regard to the supplemental report, the plaintiff contends that it is nothing more than her FDA report under a different cloak. I agree. Reading the two reports side by side, it appears that Dr. Brauer "supplemented" her report by removing references to the FDA and substituting the term "industry standard" instead. This "industry standard" clearly describes the FDA 510(k) process, which Dr. Brauer admits in her deposition. There is far too much overlap between Dr. Brauer's FDA report and supplemental report to avoid a regulatory mini-trial, which I have repeatedly and consistently held would confuse and mislead the jury. Accordingly, the plaintiff's Motion to Exclude or Limit the Testimony of Christine Brauer, Ph.D. is **GRANTED**, and Dr. Brauer's opinions are **EXCLUDED** in their entirety.

C. Lonny Green, M.D.

Dr. Green is a board certified urologist whose practice is largely focused on the treatment of female urinary incontinence and who has extensive experience with the Obtryx. Dr. Green opines that mid-urethral slings, like the Obtryx, are the standard of care in the treatment of SUI.

1. Obtryx DFU

First, the plaintiff argues that Dr. Green is not qualified to offer opinions on the Obtryx DFU because he has never written a DFU and could not describe the general requirements for a DFU during his deposition.

In the past, I allowed a doctor to testify that the DFU was inadequate because it failed to warn against risks the doctor observed in his or her own practice. In

contrast, now I must determine whether the same kind of doctor is instead qualified to offer his expert opinion that the warnings were in fact adequate. There is a clear distinction. The plaintiff's experts observed certain risks and complications in their practice and then sought to opine that those risks should have been included in the product warnings. In the present case, BSC's experts have observed certain risks and complications in their practice, which are warned of in the DFU, and therefore deduce that there are no other possible risks or complications that should have been included. The plaintiff's experts address a discrete risk which they have personally observed, while BSC's experts' opinions attempt to encompass all possible risks, none of which they have personally observed. Accordingly, I **FIND** that without additional expertise in the specific area of product warnings, a doctor, such as a urologist or urogynecologist, is not qualified to opine that a product warning was adequate, merely because it included risks he has observed in his own practice.

Dr. Green fails to address the significance of complications he has not seen in his practice, and which are not warned of in the DFU. In his deposition, Dr. Green admits he has never drafted a DFU for a medical device or pharmaceutical. Although Dr. Green indicates he has "expertise" in the process of writing patient handouts warning against drug complications, his experience appears to be limited to his review and distribution of these handouts, rather than contribution to the drafting. Accordingly, I **FIND** that Dr. Green is not qualified to opine on the adequacy of product warnings, and therefore, his opinions related to the Obtryx DFU are **EXCLUDED**.

2. FDA 510(k) Clearance

BSC concedes that Dr. Green will not offer opinions on the FDA 510(k) clearance process. Accordingly, the plaintiff's motion is **GRANTED**. Furthermore, I have repeatedly held that the probative value of FDA evidence is substantially outweighed by the risk of jury confusion. Therefore, to the extent Dr. Green seeks to offer other expert opinions on the FDA, such opinions are likewise **EXCLUDED**.

3. Physical Properties of Polypropylene

a. Qualifications

The plaintiff argues that Dr. Green is not qualified to opine that the Obtryx does not shrink, contract, degrade, or cause systemic infections. I disagree. A lack of personal experience performing pathology research on polypropylene explants does not necessarily render Dr. Green unqualified under Rule 702 to offer opinions on the suitability of the Obtryx device.

Dr. Green has performed almost 3,000 sling procedures, and his clinical practice has largely focused on the treatment of female urinary incontinence over the last twenty years. Further, Dr. Green cites numerous studies and academic papers throughout his expert report to support his opinion that the Obtryx is both safe and effective. I therefore **FIND** that Dr. Green is qualified to offer the opinion that the Obtryx mesh does not shrink, contract, degrade, or cause systemic infections. The plaintiff's motion is **DENIED** on this point.

b. Reliability

The plaintiff challenges the reliability of Dr. Green's opinion on the physical

properties of mesh—specifically that there is no evidence the device in question contracts, degrades, or causes systemic infection. Dr. Green claims he based this opinion on his clinical experience, during which he did not observe evidence of such mesh properties, and upon review of medical and scientific literature.

The advisory committee notes to Rule 702 state:

> If the witness is relying solely or primarily on experience, then the witness must explain how that experience leads to the conclusion reached, why that experience is a sufficient basis for the opinion, and how that experience is reliably applied to the facts. The trial court's gatekeeping function requires more than simply "taking the expert's word for it."

Fed. R. Evid. 702 advisory committee's note to 2000 amendment (citing *Daubert v. Merrell Dow Pharm., Inc.*, 43 F.3d 1311, 1319 (9th Cir. 1995) ("We've been presented with only the expert's qualifications, their conclusions and their assurances of reliability. Under *Daubert*, that's not enough.")).

Yet the Fourth Circuit appears more willing to "take the expert's word for it" so long as the expert has demonstrated that he or she has experience in a field writ large. *See, e.g., Eskridge v. Pac. Cycle, Inc.*, 556 F. App'x 182, 190–91 (4th Cir. 2014) (unpublished) (finding a bicycle engineer's experience with "hundreds of cases of accidents" and "decades of experience in the industry in general" provided a reliable basis to testify about whether bicycle purchasers read warnings and dismissing concerns that the bicycle expert's testimony was nothing more than personal opinion because of his "years of experience" and assurance that all of his opinions were "to a reasonable degree of engineering certainty").

On the one hand, Dr. Green has based his opinions on his extensive clinical

experience and a review of the medical and scientific literature, which, in the abstract, are reasonable bases from which to form an expert opinion. *See Kumho*, 526 U.S. at 156 ("[N]o one denies that an expert might draw a conclusion from a set of observations based on extensive and specialized experience.").

On the other hand, the court does not have enough information to judge the reliability or relevance of these particular clinical observations—as distinguished from experience examining mesh explants. Perhaps Dr. Green did not observe evidence of mesh contraction because he was not looking. Or perhaps his method of identifying and tracking the complications at issue is not scientifically sound. Additionally, sweeping statements about support within the medical community or medical literature can be difficult to assess. Although the expert report indicates Dr. Green reviewed an extensive list of literature in forming his opinions generally, the court is directed to minimal specific support for the statements at issue or detail about Dr. Green's methodology.

In this specific context, I am without sufficient information at this time to draw the fine line between reliable and unreliable expert testimony on physical mesh properties based primarily on a doctor's clinical observations, or lack thereof. Accordingly, I **RESERVE** ruling until further testimony may be offered and evaluated firsthand at trial.

For the above reasons, the plaintiff's Motion to Exclude the Opinions and Testimony of Lonny Green, M.D. is **GRANTED in part, DENIED in part**, and **RESERVED in part.**

VI. Effect of *Daubert* Ruling

I emphasize that my rulings excluding expert opinions under Rule 702 and *Daubert* are dispositive of their potential admissibility in these cases, but my rulings not to exclude expert opinions are not dispositive of their admissibility at trial. In other words, to the extent that certain opinions might be cumulative or might confuse or mislead the jury, they may still be excluded under Rule 403 or some other evidentiary rule. I will take up these issues as they arise.

VII. Conclusion

For the reasons discussed above, my rulings on BSC's motions are as follows: Motion to Exclude the Testimony of Michael Thomas Margolis, M.D. [ECF No. 44] is **GRANTED in part** and **DENIED in part**; Motion to Exclude the Opinions and Testimony of Thomas Barker, Ph.D. [ECF No. 46] is **GRANTED**; Motion to Exclude the Opinions and Testimony of Jimmy Mays, Ph.D. [ECF No. 52] is **GRANTED**; Motion to Exclude the Opinions and Testimony of Peggy Pence, Ph.D. [ECF No. 54] is **GRANTED in part, DENIED in part**, and **RESERVED in part**; Motion to Exclude the Opinions and Testimony of Russell Dunn, Ph.D. [ECF No. 55] is **GRANTED**; Motion to Exclude the Opinions and Testimony of Scott Guelcher, Ph.D. [ECF No. 56] is **GRANTED**; Motion to Exclude the Opinions and Testimony of Richard Trepeta, M.D. [ECF No. 58] is **GRANTED in part** and **DENIED in part**; Motion to Strike and Exclude the Opinions and Testimony of Vladimir Iakovlev, M.D. [ECF No. 61] is **GRANTED**; Motion to Exclude the Opinions and Testimony of Jerry Blaivas, M.D. [ECF No. 49] is **GRANTED in part** and **DENIED in part**; and Motion to Exclude the

Opinions and Testimony of William Porter, M.D. [ECF No. 57] is **DENIED in part** and **RESERVED in part.**

My rulings on the plaintiff's motions are as follows: Motion to Exclude the Opinions and Testimony of Gary L. Winn, Ph.D. [ECF No. 47] is **RESERVED**; Motion to Exclude or Limit the Testimony of Christine Brauer, Ph.D. [ECF No. 50] is **GRANTED**; and Motion to Exclude the Opinions and Testimony of Lonny Green, M.D. [ECF No. 48] is **GRANTED in part**, **DENIED in part,** and **RESERVED in part.**

The court **DIRECTS** the Clerk to send a copy of this Order to counsel of record and any unrepresented party.

ENTER: May 19, 2016

JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE